February 3, 2000

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Dockets Management Branch
The Food and Drug Administration
Department of Health and Human Services
Room 1-23
12420 Parklawn Drive
Rockville, MD 20857

Re:

99P-1340/CP 1

Petition to Have Eternity eau de parfum Misbranded

Dear Sir or Madam:

In May, 1999, the Environmental Health Network (EHN) submitted the above petition to have Calvin Klein's Eternity eau de parfum declared misbranded. I am writing because I fully support this petition and request that the FDA give it careful attention with regard to your regulations 21 CFR § 740.1, 21 CFR § 740.2, and 21 CFR 740.10. Regulation 21 CFR 740.10 specifically states:

Each ingredient used in a cosmetic product and each finished cosmetic product shall be adequately substantiated for safety prior to marketing. Any such ingredient or product whose safety is not adequately substantiated prior to marketing is misbranded unless it contains the following conspicuous statement on the principal display panel: "Warning-The safety of this product has not been determined."

As the petition shows, Eternity contains toxic ingredients and ingredients whose safety have not been substantiated. There is no warning label on its packaging.

We all have a right to know the status of safety testing of the ingredients in products such as Eternity so that we can protect ourselves and our families from toxic chemicals that may cause health problems. Most people are not aware that most fragrance materials have only limited safety testing. They wrongfully assume these products are safe to use in any setting and are surprised when people complain.

Like tobacco smoke, the harmful chemicals currently used in these products may affect the health of many people, including people with asthma, chemical sensitivities, chronic fatigue, and other environmental illnesses. Children are particularly vulnerable to toxic chemicals found in products purchased and used by their parents, caregivers, and teachers.

99P-13HO

C 576

Dockets Management Branch
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Re: 99P-1340/CP 1

Page 2

When I am exposed to fragrance products, such as Eternity, I experience headaches and even migraines after prolonged exposure. I also experience difficulty in breathing due to swelling of nasal passages and/or bronchial constriction, facial pain due to the swollen nasal passages and/or swelling of the sinus cavities, watery eyes and a feeling of general malaise with chills and sweats.

Last year I had to be hospitalized for bleeding ulcers. This was as a result of having to take numerous daily doses of pain medication in order to try to lessen the headache pain that I had to suffer because I had to share an office with someone who used body gels and/or wore cologne to work every day.

Please act on behalf of the millions of people who have suffered physical illness and injury resulting from fragrance exposure at work, in social settings, and in school. These toxic chemicals act as powerful barriers to people disabled by asthma and chemical sensitivities. Because of this, toxic chemicals have already ruined countless lives. Thank you.

Sincerely,

Susan K. DiPaola

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Susan X. De Yala





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